

Appl. No. 10/620,335
Amendment dated: July 28, 2005
Reply to OA of: May 3, 2005

REMARKS

Applicants have amended the drawings and claims to more particularly define the invention taking into consideration the outstanding Official Action. The drawings are objected to because Figures 5-8 should be designated by a legend such as "Prior Art" because only that which is old is illustrated. Accordingly, Applicants have replaced the original drawings of Figures 5-8 with corrected drawings with the legend "Prior Art" added and are found at the end of this paper marked "Replacement Sheets". Accordingly, it is most respectfully requested that this objection be withdrawn.

Claims 1 and 4 have been amended to more particularly define the invention. The limitation from claim 3 has been added to claim 1. Claims 3, 5-9, and 11-16 have been canceled without prejudice or disclaimer and new claims 17-20 have been added to specific aspects of the invention and are fully supported in lines 6-14 on page 6 of Applicants' specification and Figure 1. The amended claims are fully supported by the application as originally filed and no new matter has been introduced. Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 1-3 and 10-11 under 35 U.S.C. §102(b) as being anticipated by Zucherman '948 and claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over Zucherman has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

Applicant wishes to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical

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Amendments to the Drawings:

Please replace original drawing Figures 5-8 with the corrected drawings found at the end of this paper marked "Replacement Sheet".

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invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The device of the presently claimed invention is used for treating dysphonia, more specifically, it is implanted in the thyroid cartilage, as shown in the attached figure sheet 2, to prevent excessively tight closure of the glottis. This is a claim limitation which cannot be ignored. As in the present case, the cited references would not have taught or suggested the structure of the claimed driver in the absence of prior knowledge of Stencel's fastener system. Stencel's system is not prior art against the claims of his own patent application. Nor is obviousness established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion that the combination be made. *Interconnect Planning Corp. v. Feil*. 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985); *In re Corkill*, 771 F.2d 1496, 1501-02, 226 USPQ 1005, 1009-10 (Fed. Cir. 1985).

[I] Stencel is not inhibited from claiming his driver, limited by the statement of its purpose, and further defined by the remaining clauses of the claims at issue, when there is no suggestion in the prior art of a driver having the claimed structure and purpose. See *In re Deminski*, 796 F.2d 436, 442, 230 USPQ 313, 315 (Fed. Cir. 1986).

We conclude that it would not have been obvious to put the Grabovac flats in the Reiland driver unless one had in mind the purpose taught by appellant. This purpose, set forth in the claims themselves, "is more than a mere statement of purpose; and that language is essential to particularly point out the invention defined by the claims." *In re Bulloch*, 604 F.2d 1362, 1365, 203 USPQ171, 174 (CCPA 1979). See also *Perkin-Elmer Corp. v.Computervision Corp.*, 732F.2d 888, 896. 221 USPQ 669,

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675 (Fed.Cir.), cert. denied, 469 U.S. 857 [225 USPQ792] (1984) (the limitations appearing in the preamble are necessary to give meaning to the claim and properly define the invention).

The surgical treatment of concern with the presently claimed invention comprises incising thyroid cartilage at the midline thereof, pulling laterally and separating the incised edges of the thyroid cartilage, and setting the shim (including the inventive device and the conventional silicone prosthesis) between the incised edges to maintain the separation is known as Isshiki's operation as would be appreciated by one of ordinary skill in the art to which the invention pertains. When separating the incised edges of the thyroid cartilage, the soft tissue, i.e. perichondrium and mucous membrane, are expanded laterally.

With respect to the Isshiki's operation, utmost caution should be taken not to cut or damage the soft tissue underlying the cartilage, because the damaged soft tissue, i.e. specially torn mucous membrane of the trachea, provokes coughing.

Each of the J-shaped supporters constituting the device of the invention is made of a thin plate of titanium or alloy thereof.

As mentioned in the method of treating with use of the device, the shorter supporting part 1c is inserted between the cartilage 11 and the soft tissue 20 (referring to lines 2 to 4 on page 9 and Fig 3 of the application, and the attached sheet 2).

It is very important to make the J-shaped supporter from a thin plate, because this allows the shorter supporting part to slip and insert between the cartilage and the soft tissue. Therefore, a physician can execute Isshiki's operation easily without damaging soft tissue, particularly breaking the mucous membrane.

The device of the invention comprises a pair of J-shaped supporter and a connector joining the pair of the supporters apart from each other.

The connector's role includes maintaining the optimal distance for phonation.

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The device set on the separated incised cartilages is stressed to narrow the distance between the incised edges.

In case of the T-shaped silicone shim as shown in Fig. 7, the pressure from the separated edges pushing against the prominence 13a causes the silicone prosthesis to be forced out, if a pair of wings 13b is not fixed firmly on the incised edges.

On the other hand, in case of the device of the invention, each of the J-shaped supporters receives the pressure from the separated edges, respectively. Since the J-shaped supporter holds the edge, the device will not be able to be dislodged accidentally. This means the device of the invention will maintain the optimal distance for long-term.

Furthermore, the J-shaped supporter is superior to the U-shaped supporter for the following reason.

The length of the supporting part to be disposed on the posterior part of the thyroid is enough to make the supporter J-shape. If the posterior supporting part to be disposed on a posterior part of the thyroid is too long such as to make the supporter U-shaped, the risk of damaging the soft tissue increases when executing the Isshiki's operation.

New claim 17 recites that the left side supporting part and the right side supporting part are the same shape and size as each other.

An equivalent pressure from both the left side supporting part and the right side supporting part is obtained from the incised edge of the cartilage respectively. Therefore, it is preferable that the supporters on either side of the connector be symmetrical.

The device of new claim 18 may secure the space between the connector and the soft tissue, in the condition that the device is set on the thyroid cartilage.

The space can prevent the connector from contacting the soft tissue, and thus decreases the risk of damaging the soft tissue.

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The advantage of the device of claim 10 is that each supporter is formed with through-holes for passing suture through there.

The thyroid cartilage is movable up and down, when stirring the larynx in the neck, for example nodding his or her head, or tilting his or her chin upwardly/downwardly.

Therefore, if the device is not fixed firmly on the edge of the incised thyroid, the device may slip along the groove of the incised thyroid cartilage, this may impair the effect of treatment. This is why there is a need to have the optimal distance of the separation of the incised edges secured by two devices fixed at the upper and lower portions at the midline of the thyroid cartilage (please refer to Fig.8 of the specification and the attached sheet 2).

As described in the 3rd paragraph on page 6 of the specification, since the distance (*t*) between the longer supporting part and the shorter supporting part is usually designed to be larger than the thickness of the thyroid cartilage, the supporters are required to be fastened to the thyroid cartilage by suture. The through-holes formed in each supporter make it easier to fix the supporter to the thyroid cartilage by suture.

The device disclosed in Zucherman, especially embodiment shown in Figs 74 to 78, has the following features.

The device of Zucherman is used for expanding the volume in the spine canal and/or neural foraman (see Abstract).

And the device includes a spinal column extension stop and a spinal column flexion non-inhibitor (see lines 36 to 41 in col.1).

This device is adapted to increase the volume of the spinal canal and/or the neural foraman as the device is positioned between adjacent spinous processes of the spinal column (see lines 48 to 51 of col.1).

A spine is very tough and stiff compared with the thyroid cartilage.

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Inserting the device between the adjacent spinous processes is different from inserting the device between the thyroid cartilage and soft tissue underlying the thyroid cartilage. The operation with use of Zucherman's device does not require such caution not to cut or damage soft tissue like membrane.

As shown in Figs.74 to 78, the central body corresponding to the connector of the present invention is thick, i.e. the central body is never made form a thin plate.

Since the central body is positioned between the adjacent spinous processes, the central body is required to have volume for enlarging the volume of spinal canal.

A pair of the saddle 706 and 708 corresponds to a pair of J-shaped supporter of the present invention. However, the saddle is different from the supporter.

As described in lines 3 to 20 of col. 16 and shown in Figs 74 and 78, the first and second arms 710 and 712 of the saddle 706 have different length from the third and fourth arms 714 and 716 of the saddle 708 respectively. That is to say, the saddles on either side of the central body are not symmetrical, while the supporters on either side of the connector are symmetrical.

Please note that the saddles are designed in such a way that the device can be easily and conveniently inserted between the adjacent spinous processes.

A bore, i.e. through-hole, is formed in the central body, as recited claim 6 and shown in Figs 74 and 78.

The bore is used in order to adjust the modulus of elasticity of the implant, as described in lines 22 to 27 of col.4, lines 60 to 63 of col.15, claim 7 and so on.

Furthermore, the bore contributes to make the device of Zucherman flexible in order to reduce potential resorption of the bone (see line 63 of col. 15 to line 2 to col.2).

Further, please note that Zucherman has a through-hole in the central body corresponding to the connector of Isshiki's device, while Isshiki's device has through-holes in the supporters corresponding to the saddles of Zucherman's device.

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Applicants further wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification.

The device of the present invention is different from one disclosed in Zucherman.

Issiki's device is used for treating dysphonia by securing the optimal distance between the edges of the incised thyroid cartilage. On the other hand, Zucherman's device is implanted between adjacent spinous processes for expanding the volume in the spine column.

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Since the use of Zucherman's device, i.e. the place to be positioned, is different from the use of Isshiki's device, Zucherman does not disclose the requirements for Isshiki's operation. In other words, Zucherman never teach a design appropriate for implanting the device between the thyroid cartilage and the soft tissue.

The J-shaped supporter made of a thin plate in Isshiki's device is different from the saddle in Zucherman's device.

Since spine is very tough, Zucherman provides no motivation to make a saddle of a thin plate for inserting between the cartilage and the soft tissue so not as to damage and break the cartilage and the soft tissue.

Zucherman states unsymmetrical design is preferable as mentioned above (see feature (c) of Zucherman). However, Isshiki's device requires a symmetrical design for the stability of the device, which is set on the thyroid cartilage (see feature (d) of Isshiki).

Therefore, Zucherman's device differs from Isshiki's device.

The connector, which is made of a thin plate in Isshiki's device, is different from the central body of Zucherman's device.

Isshiki's device requires the thin plate connector as described in feature (e). However, Zucherman's device requires that the central body has volume, as mentioned in feature (b) of Zucherman,

Therefore, Zucherman teaches away from the present invention.

In regard to a through-hole, positioning and purpose of Zucherman's device are different from those of Isshiki's device (refer to feature (f) of Issiki and feature (d) of Zucherman).

Zucherman's device is to be set in tough and stiff tissue, that is, between spinous processes of the spine column. Therefore, Zucherman provides no motivation to fix the device by suture. Accordingly, Zucherman never teaches a through-hole formed in the saddles corresponding to the supporter.

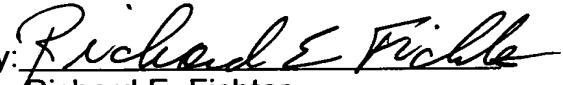
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Furthermore, according to the present invention, the width (d) of the connector is determined for securing the optimal distance for phonation, therefore, the connector excludes a through-hole for adjusting the modulus of elasticity. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the drawings and claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By: 
Richard E. Fichter
Registration No. 26,382

625 Slaters Lane, 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

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